

# **EXHIBIT A**

## SUMMONS

Attorney(s) Hillel I. Parness, PARNESS LAW FIRM, PLLC  
Office Address 136 Madison Ave., 6th Floor  
Town, State, Zip Code New York, NY 10016  
Telephone Number 212-447-5299  
Attorney(s) for Plaintiff Novel Laboratories, Inc.  
Novel Laboratories, Inc.

Plaintiff(s)

Vs.  
KVK-Tech, Inc. and Gator Pharmaceuticals, Inc.

Defendant(s)

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at [http://www.judiciary.state.nj.us/prose/10153\\_deptyclerklawref.pdf](http://www.judiciary.state.nj.us/prose/10153_deptyclerklawref.pdf).) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of \$175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at [http://www.judiciary.state.nj.us/prose/10153\\_deptyclerklawref.pdf](http://www.judiciary.state.nj.us/prose/10153_deptyclerklawref.pdf).

  
Michelle M. Smith, Clerk  
Clerk of the Superior Court

DATED: 1/20/17

Name of Defendant to Be Served: KVK-Tech, Inc.

Address of Defendant to Be Served: 110 Terry Drive, Suite 200 Newtown, PA 18940

## Superior Court of New Jersey

Somerset COUNTY  
Law DIVISION  
Docket No: Sum-L-70-17

## CIVIL ACTION SUMMONS

**PARNES LAW FIRM, PLLC**  
136 Madison Ave., 6<sup>th</sup> Floor  
New York, NY 10016  
212-447-5299  
*Attorneys for Plaintiff*

---

**NOVEL LABORATORIES, INC.,**

**Plaintiff,**

**v.**

**KVK-TECH, INC. and GATOR  
PHARMACEUTICALS, INC.**

**Defendants**

---

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: SOMERSET COUNTY**

**DOCKET NO. SOM-L-\_\_\_\_\_**

**COMPLAINT**

Plaintiff, Novel Laboratories, Inc. (“Novel”), through its undersigned counsel, by way of Complaint against defendants KVK-Tech, Inc. (“KVK”) and Gator Pharmaceuticals, Inc. (“Gator”) (KVK and Gator, collectively, “Defendants”), hereby says:

**JURISDICTION AND VENUE**

1. This Court has jurisdiction over Defendant KVK because the cause of action arose out of Defendant’s contacts with this State, namely the entry into a contract on the record in New Jersey Superior Court with Novel, a New Jersey resident, and KVK’s subsequent breaches of that contract.

2. This Court has jurisdiction over Defendant Gator because Gator tortuously interfered with a contract entered into between Novel and KVK that was entered into in this State, or because Gator is the alter ego of KVK, or both. Gator has sufficient minimum contacts with New Jersey to make it reasonable that it would be sued in New Jersey, and those minimum contacts gave rise to the injury claimed by Novel.

3. Venue for this action properly lies in Somerset County, pursuant to R. 4:3-2(a), because Plaintiff Novel resides in Somerset County, New Jersey.

**THE PARTIES**

4. Plaintiff Novel is a generic pharmaceutical company located at 390 Campus Dr., Somerset, NJ 08873.

5. Defendant KVK is a generic pharmaceutical company located at 110 Terry Drive, Suite 200, Newtown, PA 18940.

6. Defendant Gator is an entity that purports to be located at 194 Inlet Dr., Saint Augustine, Florida 32080-3813. Upon information and belief, Gator is the alter ego of KVK.

**FACTS**

**Background of Generic Pharmaceutical Approval Procedures**

7. Plaintiff Novel<sup>1</sup> is engaged in the development and manufacture of technology-driven generic pharmaceuticals. Novel was founded in 2006 and developed a strong reputation in its industry due to its ability to identify and develop new generic drug products. Novel expends considerable time and resources in its efforts to determine whether a brand-name pharmaceutical is suitable for the generic market. Once Novel determines that a product is suitable, it undertakes the time-consuming process of developing the product and preparing an Abbreviated New Drug Application (“ANDA”) for filing with the United States Food and Drug Administration (the “FDA”). The first party that files an ANDA with respect to certain generic products is entitled to the exclusive right to market the product for 180 days upon FDA approval of the ANDA.

8. Due to the strong financial incentive tied to being the first company to file an ANDA,

---

<sup>1</sup> Lupin, Inc. acquired Novel on March 8, 2016. Lupin, Inc., a Delaware corporation, is indirectly wholly owned by the ultimate parent company Lupin Limited (“Lupin”). Lupin continues to operate Novel as a separate entity.

the identity of any products that Novel is developing or has determined to be suitable for development constitutes proprietary and highly confidential information. Based on Novel's reputation in the generics industry, the knowledge that Novel has determined that a product is suitable for generic development and production is extremely valuable to Novel's competitors. If one of Novel's competitors gains access to Novel's business plans and other proprietary information, that competitor could usurp the information Novel compiles through extensive market, regulatory and intellectual property analysis for great financial and reputational benefit to the detriment of Novel. This is what happened, and why Novel brought this action against KVK and others in 2011.

**Novel Secretly Developed a Generic Version of SUPREP**

9. In 2007, former Defendant Muthusamy Shanmugam joined Novel as the Vice President of Technical Operations and was the head of product development. In such capacity, Shanmugam was extensively involved in all aspects of the research and development efforts for generic pharmaceuticals, including product identification and selection. Shanmugam attended regular planning meetings and held regular discussions with Novel's leadership regarding the highly confidential aspects of new product developments and ANDAs. Shanmugam played a central role in the daily operations of Novel and he had access to all confidential information concerning products in development and Novel's business and marketing strategies.

10. Novel began researching and developing a generic version of SUPREP in 2009, a fact that Shanmugam became aware of by virtue of his position at Novel.

11. Shanmugam was terminated for cause on May 17, 2010, after Novel learned that he had breached his employment and confidentiality agreements with Novel. Specifically, Novel terminated Shanmugam because he was providing consulting and other services to a competitor of

Novel, collaborating with that competitor in developing products, and soliciting Novel employees to consult with and develop products for that competitor.

12. After Shanmugam's termination, Novel discovered that KVK and Shanmugam were developing a generic version of SUPREP through an entity newly-formed for that purpose (Amrutham), and that they planned to file an ANDA with respect to that product in Amrutham's name.

13. In October 2010, after Novel confronted KVK, KVK's counsel assured Novel multiple times in writing that KVK would not move forward with a generic alternative to SUPREP, writing on October 22, 2010: "KVK is not proceeding with any work on [SUPREP], and will not while discussions continue amongst the parties. As before, I can assure you that if KVK's position changes in this regard, we will notify you before proceeding."

14. Novel refrained from suing defendants in reliance on defendants' counsel's representations, but KVK reneged on its representations and took advantage of Novel's good faith. KVK filed the KVK ANDA and a declaratory judgment action against Novel in Pennsylvania, both without advance notice to Novel.

### **Novel Sued KVK for Misappropriation of Trade Secrets**

15. After learning of the violation of their standstill arrangement, Novel sued KVK and its co-defendants on February 3, 2011. Defendants were using – and were poised to continue using – the misappropriated confidential and proprietary information, including Novel's determination that SUPREP was an appropriate target for generic formulation, as well as the generic formulation itself. Novel therefore asked for broad injunctive relief relating in any way to SUPREP (defined as the "Product" in the complaint), including:

- a. "injunctive relief enjoining Shanmugam from further disclosure of Confidential

Information regarding the Product”;

- b. “injunctive relief enjoining Shanmugam from further business or activities with respect to the Product”;
- c. “injunctive relief enjoining Shanmugam, KVK and Amrutham from developing the Product”; and
- d. “injunctive relief enjoining KVK and Amrutham from developing the Product and engaging in further tortious acts.”

16. Five days after Novel initiated the suit, the Court granted Novel’s request for injunctive relief against KVK and its co-defendants.

#### **Novel and KVK Entered Into the Settlement Agreement**

17. On October 3, 2012, the parties appeared before the Court and represented that they had reached an agreement on settlement. At the Court’s direction, the parties put the terms of settlement on the record, the Court pronounced the case “settled, based on this agreement,” and the Court further confirmed that the parties understood the settlement was final.

18. Specifically, Novel’s counsel set forth the following terms:

Upon the launch of the product that was at issue in this litigation, 30 days thereafter, we’ll make the first payment to Defendants of \$250,000, and over the next eight years will pay a total of another \$750,000. In exchange, the Defendants will, as soon as Novel is obligated to make that payment, they’ll withdraw their application, the Abbreviated New Drug Application that had been filed with the FDA, and between now and then have agreed not to take any efforts to market the product, including putting it on any pipeline for their customers, or otherwise any potential customers about the product as being a product that they have.

....

It doesn’t have to be paid until 30 days after the launch of Novel’s product. But it’s obviously known that it has to be paid before that. And at that point they withdraw their application. But between now and then they won’t do anything to promote it, tell people it’s in the

pipeline, etcetera.

....

[B]oth Defendant KVK-Tech and Amrutham would also, individuals of the covenants of a period that he won't be able to do formulations, etcetera and so forth.

....

The settlement will include that if there's a breach by the Defendants, of the settlement, they will have to repay any amounts paid to them, as well as retroactively attorneys fees for such a breach.

....

[T]here will be penalties if Novel fails to make the payments under this agreement....There will also be certain provisions of the settlement that will be anti-circumvention, making sure that Novel doesn't find a way to get out of its obligation by going out of business.

19. KVK's counsel did not dispute any of the foregoing, but added that the purpose of the anti-circumvention provision, which required Novel to transfer its payment obligation to any subsequent company, "is to make sure that there's no circumvention of the overall spirit of the agreement."

20. After settlement was reached at the October conference, the parties turned to drafting a written agreement to memorialize the terms. Only two drafts were exchanged. Novel sent KVK a draft agreement on October 25, 2012, but KVK did not send Novel a counterdraft until January 18, 2013.

21. Both drafts, however, contained the following three sections – unchanged from the October 2012 draft to the January 2013 draft – under the heading "8. KVK Parties' Representations and Covenants":

c. The KVK Parties represent and warrant that, as of the Effective Date, none of the KVK Parties have provided any information about the formulation nor provided, transferred, assigned, sold or promised

to any other entity the formulation for any generic version of the Brand Product.

d. The KVK Parties covenant and agree that, as of the Effective Date and at any time thereafter, none of the KVK Parties will develop, manufacture, market, obtain any commercial benefit from, or transfer, assign, sell or promise to any other person or entity, the generic version of the Brand Product or the Amrutham ANDA, nor will the KVK Parties induce any third party to engage in any actions described in this Paragraph. Such prohibited marketing efforts include, but are not limited to, (i) any attempts to sell the Brand Product or the Amrutham ANDA or the Amrutham ANDA product, (ii) informing the KVK Parties' customers, potential customers or potential marketing partners that the Amrutham ANDA product is one they intend to sell or launch or is one for which they are awaiting approval, (iii) including the Amrutham ANDA product on a list of products in KVK or Amrutham's pipeline, and (iv) informing their customers or potential customers of potential launch dates for the Amrutham ANDA Product.

e. The KVK Parties covenant and agree that, as of the Effective Date and at any time thereafter, none of the KVK Parties, have recreated or will recreate the generic formulation of the Brand Product reflected in the Amrutham ANDA, create a new formulation of the Brand Product, or inform or work with any other person or entity to formulate, file an ANDA for or otherwise develop, manufacture or market any other version of the Brand Product, without regard as to whether such version is to be marketed as a brand, generic or over-the-counter medicament, nor will the KVK Parties induce any third party to engage in any actions described in this Paragraph.

### **KVK Breached the Settlement Agreement**

22. As noted above, under the Settlement Agreement KVK agreed to withdraw the KVK ANDA when certain conditions were met, and agreed to refrain from developing or being involved with the development of any other formulations of generic SUPREP, in exchange for a future payment from Novel of \$1 million.

23. Soon thereafter, however, Novel learned that KVK had already breached the Settlement Agreement by filing a New Drug Application (the "paper-NDA") with the FDA for a generic version of SUPREP. The paper-NDA concerned a powder-based generic version of

SUPREP, whereas the original KVK ANDA concerned a liquid-concentrate-based generic version.

**The Court Holds that KVK Breached the Settlement Agreement and Ordered Compliance**

24. On July 24, 2013, Novel brought a Motion to Enforce the Settlement Agreement before the Court. On October 9, 2013, the Court ruled that KVK had breached the Settlement Agreement and ordered KVK to immediately withdraw the paper-NDA (Parness Cert. Ex. 1), writing, in pertinent part (emphasis added):

Plaintiff's motion shall be granted. As stated above, under the terms of the agreement, the Plaintiffs were to pay the Defendants \$1 million over 8 years if: (i) their generic version of the product was approved by the FDA and (ii) Plaintiff cleared the patent issues with the brand name manufacturer, Braintree Laboratories, Inc. At the time both prongs were met, Defendants would withdraw their application for their generic version of the brand name product. Additionally, the Defendants agree they would not "be able to do formulations, etcetera and so forth." This Court believes Defendant's paper-NDA is a formulation of SUPREP under the settlement agreement that was put on the record. This Court reads the settlement as Defendants being prohibited from any formulations that involve SUPREP. The powder paper-NDA is the bioequivalent of the liquid product that was at the heart of the settlement agreement and the Defendant must abide by the settlement agreement and not create formulations of SUPREP until the Plaintiff has cleared the patent issues with Braintree.

25. In its accompanying Order issued on October 10, 2013 (Parness Cert. Ex. 2), this Court ordered that "(1) defendants shall immediately withdraw their new paper-NDA application; [and] (2) defendants shall refrain from filing any further applications of any kind relating to formulations of any kind of SUPREP."

**The Court and the Appellate Division Rejected KVK's Arguments Regarding Gator**

26. KVK then sought amendment or reconsideration of the Court's Order, on grounds that included its powerlessness to withdraw the paper-NDA, because KVK had purportedly filed the application on behalf of another company, Defendant Gator Pharmaceuticals, Inc. ("Gator"). On February 3, 2014, KVK's motion was denied (Parness Cert. Ex. 3), the Court writing, in pertinent

part (emphasis added):

First, the Defendants' argument that they cannot control Gator because Gator is a separate and distinct corporation should have been raised during oral argument or through their motion papers. The Defendants claim the Plaintiff and Court were aware of Gator being the sole entity that submitted the application for the paper-NDA. Defendants point to the FDA Tentative Approval letter which is addressed as KVK "on behalf of" Gator and that KVK's role was assisting Gator in the preparation and filing of the application. The Court cannot infer from those documents that KVK's role was simply assisting Gator in the preparation and filing of the application. Defendants were aware of the consequences if the Court granted the Plaintiffs motion. Defendants had the opportunity to address the consequences with Gator prior to oral argument and neglected to inform this Court or Plaintiff that Gator controls all aspects of the drug formulation process. Thus, Defendants' argument to amend the Order because of Gator's refusal to consent fails.

27. KVK then appealed to the New Jersey Superior Court, Appellate Division, which on February 3, 2015 affirmed the Court's decisions in their entirety (Parness Cert. Ex. 4), writing, in pertinent part (emphasis added):

The plain terms of a settlement agreement must be enforced, as we have explained, unless they were procured by fraud or compelling reasons exist to withhold their implementation. Nolan, *supra*, 120 N.J. at 472. Here, the oral settlement that was placed on the record clearly was not limited to merely requiring defendants to withdraw the ANDA for their Amrutham Drug and thereafter not market it, as defendants would urge. Rather, it also precluded defendants from developing "formulations, etcetera and so forth" of SUPREP.

....

We find it indicative of the scope of the parties' agreement that Paragraph 8(e) of both draft versions provides that:

None of the [defendants] have recreated or will recreate the generic formulation of the Brand Product reflected in the Amrutham ANDA, create a new formulation of the Brand Product, or inform or work with any other person or entity to formulate, file an ANDA for or otherwise develop, manufacture or market any other version of the Brand Product, without regard as to whether such version is to be marketed as a brand, generic or over-the-counter medicament.

....

The record in this case reveals that both SUPREP and Gator's Drug are composed of the same active ingredients and in the exact same proportions. They differ only in their inactive ingredients and their form, SUPREP being a berry-flavored liquid solution, while Gator's Drug is a lemon-flavored powder that needs to be mixed with water. Thus, Gator's Drug is a different formulation of SUPREP. It falls within the scope of activities that defendants agreed to forego because of Novel's \$1,000,000 payment.

....

We similarly reject defendants' alternative argument that they are unable to comply with the enforcement order, which requires them to "immediately withdraw their new paper-NDA application."....Here, defendants' argument on reconsideration that they cannot control Gator because Gator is a separate and distinct entity that submitted the application for the powder product is seemingly inconsistent with defendant's original characterization of Gator as a partner in that venture. In any event, the motion judge correctly concluded that defendants were aware of this information and had the opportunity to assert this argument in their initial opposition to the enforcement motion but failed to do so.

28. Following the Appellate Division affirmance and the New Jersey Supreme Court's denial of certification (Parness Cert. Ex. 5), however, KVKG did not withdraw the paper-NDA.

29. Instead, KVKG and Gator did the following:

- A. By letter to the FDA dated May 29, 2015 (Parness Cert. Ex. 6), Gator purported to "revoke[] KVKG Tech's agency status regarding this NDA."
- B. By letter to the FDA dated June 10, 2015 (Parness Cert. Ex. 7), KVKG "ask[ed] that the NDA be withdrawn," but then immediately continued with "we feel compelled to note for you that KVKG-Tech does not contend that it is the legal owner of NDA 204553. Indeed, as FDA records reflect, the NDA is owned by a different company, Gator Pharmaceuticals, Inc. Although KVKG-Tech did act as Gator Pharmaceuticals' agent in filing the NDA, Gator Pharmaceuticals, in its capacity as the NDA holder, has since terminated KVKG's agency and advised KVKG-Tech that KVKG-Tech is not authorized to withdraw the NDA on its behalf. We understand that Gator Pharmaceuticals has filed the enclosed correspondence with the agency confirming this position." These arguments had been

explicitly rejected by both this Court and the Appellate Division.

- C. Throughout this time period, beginning on May 28, 2015 (Parness Cert. Ex. 8) (the day before the Gator letter to the FDA), Novel's counsel made repeated inquiries of KVK's counsel as to the status of KVK's compliance with this Court's October 2013 Order.
- D. KVK's counsel avoided responding to Novel's inquiries, and did not advise Novel of either the May 29 or June 10 letters until well after they had both been submitted, on June 12, 2015.

**The Court Denied Novel's Second Motion to Enforce the Settlement Agreement and to Enforce the 2013 Order**

30. On September 2, 2015, Novel moved this Court for an Order enforcing the Settlement Agreement and the October 2013 Order, and directing KVK to actually withdraw the paper-NDA. In the alternative, if KVK was unable to comply with said Order, Novel moved for an Order directing KVK to pay Novel damages to compensate it for KVK's breach of the Settlement Agreement. Novel further moved for an Order finding KVK in contempt and imposing monetary sanctions upon KVK, including an order directing KVK to pay Novel's costs and attorney's fees.

31. On October 9, 2015, this Court denied Novel's motion on the ground that it was unripe, explaining in its Opinion and Order (Parness Cert. Ex. 9) as follows (emphasis added):

The Court finds that it cannot grant the plaintiffs motion because there is no appropriate relief which may be granted. The Court notes that neither the plaintiffs nor Gator's products have been approved by the FDA, and as such, plaintiff has not suffered any damages as a result of defendant's conduct. Thus, to grant plaintiffs motion at this juncture would be premature and inappropriate.

Further, the Court finds that defendant has not engaged in any conduct that would merit sanctions or an award of attorney's fees to plaintiff. Defendant has done all that it could to comply with the Court's Order by requesting that the paper-NDA be withdrawn, and the Court finds that the alleged twenty-two (22) day delay was not so egregious as to require such a finding.

**Novel Settles Its Patent Litigation with Braintree**

32. On August 5, 2016, Novel and SUPREP manufacturer Braintree settled their pending

patent litigation (Parness Cert. Ex. 10). The terms of that settlement are confidential, but the resolution allows Novel to move forward on its original ANDA, and to take its product to market in the future without further opposition from Braintree.

### **The FDA Approves the Paper-NDA**

33. On December 27, 2016, the FDA approved the paper-NDA (Parness Cert. Ex. 11). Among the papers released by the FDA on December 27, 2016, was the FDA-approved packaging for the powder-based generic formulation of SUPREP. That packaging document (Parness Cert. Ex. 12) shows that KVK is still working with Gator on the paper-NDA, and that KVK continues to violate the Settlement Agreement and this Court’s October 2013 Order. The materials indicate that the drug is “Manufactured for: Gator Pharmaceuticals,” directing consumers to contact KVK for more information, providing KVK’s website and KVK’s telephone number. The 215-579-1842 number is also shown on the “Contact Us” page from KVK’s website (Parness Cert. Ex. 13), [www.kvktech.com](http://www.kvktech.com).

34. The packaging (Parness Cert. Ex. 12) also indicates that the manufacturer of the product is Manufacturer Code 10702, which is the code for KVK, as reflected on the packaging of other KVK-manufactured drugs available on KVK’s website (exemplar at Parness Cert. Ex. 14). KVK is also indicated on the packaging (Parness Cert. Ex. 12) as the “Customer” of the printing and packaging company, and the packaging lists KVK, not Gator, as the company to call in the event of adverse reactions to the drug, once again providing KVK’s Pennsylvania telephone number.

35. These new documents strongly suggest that KVK is manufacturing, or getting ready to manufacture, a generic version of SUPREP, in apparent violation of the 2012 Settlement Agreement and the 2013 Order.

**COUNT ONE**  
**(Breach of Contract – against Novel)**

36. Novel repeats and realleges each and every allegation set forth above as if fully set forth herein.

37. On October 3, 2012, Novel and KVK entered into the Settlement Agreement.

38. As part of the Settlement Agreement, KVK agreed, *inter alia*, to permanently stop and refrain from developing, manufacturing, marketing, obtaining any commercial benefit from, or transferring, assigning, selling or promising to any other person or entity, any generic version or formulation of SUPREP, and to permanently stop and refrain from inducing any third party to engage in any of the foregoing.

39. As part of the Settlement Agreement, KVK also agreed, *inter alia*, to permanently stop and refrain from creating any generic version or formulation of SUPREP, or from informing or working with any other person or entity to formulate, file an ANDA for or otherwise develop, manufacture or market any other version of SUPREP, and to permanently refrain from inducing any third party to engage in any of the foregoing.

40. KVK breached the Settlement Agreement in numerous ways, including but not necessarily limited to preparing and filing the paper-NDA for a powder-based generic formulation of SUPREP, and/or directing, inducing or assisting Gator or others in connection with the same.

41. KVK has also breached the Settlement Agreement by preparing or directing the preparation of the paperwork to accompany a powder-based generic formulation of SUPREP, and/or directing, inducing or assisting Gator or others in connection with the same.

42. KVK has also breached the Settlement Agreement by manufacturing, or making preparations to manufacture, a powder-based generic formulation of SUPREP, and/or directing,

inducing or assisting Gator or others in connection with the same.

43. KVK has also breached the Settlement Agreement by serving, or preparing to serve, as the point of contact for questions about a powder-based generic formulation of SUPREP, and/or directing, inducing or assisting Gator or others in connection with the same.

44. KVK has also breached the Settlement Agreement by serving, or preparing to serve, as the point of contact for reports of adverse inferences about a powder-based generic formulation of SUPREP, and/or directing, inducing or assisting Gator or others in connection with the same.

45. Novel has been damaged by KVK's breach of the contract in an amount to be determined at trial.

**COUNT TWO**  
**(Breach of Contract – against Gator)**

46. Novel repeats and realleges each and every allegation set forth above as if fully set forth herein.

47. Upon information and belief, Gator is the alter ego of Novel.

48. As the alter ego of Novel, all of the breaches committed by Novel in Count One were also committed by Gator, and are asserted herein against Gator as if fully set forth herein.

49. Novel has been damaged by Gator's breach of the contract in an amount to be determined at trial.

**COUNT THREE**  
**(Misappropriation of Trade Secrets – against KVK and Gator)**

50. Novel repeats and realleges each and every allegation set forth above as if fully set forth herein.

51. Novel's confidential and proprietary information, including its identification of SUPREP as a drug for which generic formulations should be prepared and marketed, as well as

Novel's work in connection with the same, constituted confidential and proprietary information of Novel.

52. Novel took precautions to maintain the secrecy of its confidential and proprietary information.

53. KVK misappropriated Novel's confidential and proprietary information, or knowingly received Novel's confidential and proprietary information, through the corporate espionage detailed in Novel v. KVK I.

54. KVK has shared the confidential and proprietary information misappropriated from Novel with Gator.

55. Upon information and belief, from the moment KVK shared such confidential information with Gator, Gator knew that it had been misappropriated from Novel.

56. KVK and Gator have used, and continue to use, the confidential and proprietary information misappropriated from Novel, including in connection with KVK's and Gator's filing and advancement of one or more applications with the FDA for generic formulations of SUPREP, and in connection with their actions taken in preparation for the manufacture of such formulations.

57. Novel has been, and continues to be, damaged by KVK's and Gator's misappropriation of confidential and proprietary information and continues to be damaged by KVK's and Gator's continued use of them.

58. The actions of KVK and Gator were willful, wanton and carried out in deliberate violation of Novel's rights.

59. Novel is entitled to monetary damages in an amount which cannot be determined at this time to compensate Novel for the harm it has suffered because of the actions of KVK and Gator, plus punitive damages in an amount to be determined at the time of trial.

60. Moreover, Novel has suffered and will suffer damages including but not limited to (i) the irreparable diminution of the value of its own generic formulations of SUPREP and other undetermined products; (ii) the irreparable diminution of Novel's potential business income; and (iii) irreparable harm to Novel's reputation in the industry.

**COUNT FOUR**  
**(Tortious Interference with Contract – against Gator)**

61. Novel repeats and realleges each and every allegation set forth above as if fully set forth herein.

62. Novel and KVK entered into the Settlement Agreement on October 3, 2012.

63. Gator has surely always been aware of the Novel-KVK lawsuit, and was made aware of the Settlement Agreement that ended that lawsuit immediately upon entry. At the very least, KVK has affirmatively represented to this Court that after the entry of the October 2013 Order, KVK made Gator aware of it, and Gator refused to consent to KVK's withdrawal of the paper-NDA.

64. Gator also intentionally and maliciously, with motive to harm and without justification, interfered with the Novel-KVK Settlement Agreement, inducing, procuring and causing KVK to breach it.

65. Specifically, but certainly not exclusively, with full knowledge that KVK had agreed to refrain from further involvement with any formulations of SUPREP, in any form, Gator – according to its own statements – retained KVK as its agent for the preparation and filing of an application for the powder-based generic formulation reflected in the paper-NDA.

66. In addition, Gator induced, procured and caused KVK to further violate the Settlement Agreement and the subsequent October 2013 Order, when it orchestrated a fraud upon the FDA with regard to Gator's purported refusal to allow KVK to withdraw the paper-NDA.

67. In addition, Gator has continued to induce, procure and cause KVK to breach the

Settlement Agreement by instructing KVK to prepare the paperwork to accompany the powder formulation of the drug (as reflected in Parness Cert. Ex. 12), instructing KVK to serve as point of contact for questions about the drug and for reporting of adverse reactions, and – most significantly, instructing KVK to be the manufacturer of the drug, all of this after Gator purportedly revoked KVK’s agency status.

68. Novel has been damaged by Gator’s interference, as it has deprived Novel of the benefit of the bargain of the Settlement Agreement – namely, peace as to the claims Novel asserted against KVK in the original litigation, the assurance that KVK would permanently step out of the marketplace for generic formulations of SUPREP, and the assurance that neither KVK nor anyone else would benefit from KVK’s misappropriation of Novel’s confidential and proprietary trade secrets.

69. Novel has been damaged by Gator’s tortious interference with the Novel-KVK Settlement Agreement in an amount to be determined at trial.

**COUNT FIVE**  
**(Fraud – against KVK and Gator)**

70. Novel repeats and realleges each and every allegation set forth above as if fully set forth herein.

71. Separate and apart from the Defendants’ breaches of the Settlement Agreement, violations of this Court’s October 2013 Order, and tortious interference with the Settlement Agreement, KVK and Gator orchestrated a series of frauds upon Novel, the FDA and this Court, directly damaging Novel as a result.

72. In October 2013, this Court ordered KVK to withdraw the paper-NDA that had been filed with the FDA. KVK argued, first on its motion for reargument, and then on its unsuccessful appeal, that it did not have the power to withdraw the paper-NDA, because that power resided with

Gator.

73. The Court and the Appellate Division both explicitly rejected this argument, reiterating this Court's October 2013 Order that KVK withdraw the paper-NDA.

74. KVK and Gator then made multiple representations to Novel, the FDA and this Court in support of that rejected argument. These included, but are not necessarily limited to, the following:

- a. On November 5, 2013, in support of KVK's motion for reconsideration, Frank Ripp, Jr., an officer of KVK, certified under penalty of perjury that "KVK filed the Section 505(b)(2) NDA application on behalf of Gator Pharmaceuticals, Inc. ("Gator"), which is an entity that is separate and distinct from Defendants, and over which Defendants have no control."
- b. Mr. Ripp further certified that "KVK has no ability to withdraw the application without Gator's consent."
- c. Mr. Ripp further certified that "KVK requested Gator's consent to withdraw the application and Gator refused, on the basis that it is not a party to this action and therefore is not subject to this Court's jurisdiction."
- d. On January 21, 2014, at the hearing on KVK's motion for reconsideration, counsel for KVK represented to the Court that "KVK could withdraw the application, but only if Gator consents, because KVK filed the application on behalf of Gator. It's -- Gator owns the application. KVK assisted in the filing of it."
- e. Counsel for KVK further represented to the Court that "after the Court came down with its ruling -- and we submit this in our certifications -- KVK went to

Gator, sent the order to Gator, and Gator looked at it and got back to us and said, look, our position is that we're not a party to this action; so we're not subject to the Court's order. So we don't give you permission to withdraw it."

- f. On May 29, 2015, Mr. Paul Burlaga of Gator wrote a letter to the FDA in which he stated: "As your records will reflect, Gator Pharmaceuticals Inc. ("Gator") submitted the above referenced NDA on November 30, 2012 via its agent, KVKTech Inc. I write this letter to inform you that, **EFFECTIVE IMMEDIATELY**, Gator hereby revokes KVKTech's agency status regarding this NDA."
- g. On June 10, 2015, Mr. Anthony Tabasso of KVKTech wrote to a letter to the FDA in which he stated: "Indeed, as FDA records reflect, the NDA is owned by a different company, Gator Pharmaceuticals, Inc. Although KVKTech did act as Gator Pharmaceuticals' agent in filing the NDA, Gator Pharmaceuticals, in its capacity as the NDA holder, has since terminated KVKTech's agency and advised KVKTech that KVKTech is not authorized to withdraw the NDA on its behalf."
- h. On June 17, 2015, in support of KVKTech's opposition to Novel's motion to enforce the Settlement Agreement, Mr. Tabasso declared under penalty of perjury that "KVKTech and Gator Pharmaceuticals, Inc. (Gator) are independent companies. KVKTech does not own Gator, and Gator does not own KVKTech. KVKTech does not have common ownership or share management with Gator."
- i. Mr. Tabasso further declared that "KVKTech has no control over Gator's business decisions, and cannot order or cause Gator to make or execute any business

decisions. Neither can KVK order or cause Gator to refrain from making or executing any business decisions.”

- j. Mr. Tabasso further declared that “KVK does not own New Drug Application 294553 (the Gator NDA) that is the subject of this litigation. To the best of my knowledge and belief, Gator owned, and still owns, the Gator NDA.”
- k. Mr. Tabasso further declared that “KVK has not been an authorized agent in the Gator NDA since Gator revoked KVK’s agency on May 29, 2015. On June 10, 2015, KVK sent FDA a notice requesting-FDA to withdraw the Gator NDA. Since this was after Gator revoked KVK’s agency, I believe that the notice has no legal effect.”

75. These statements, individually and collectively, were intended to make Novel, the FDA and the Court believe that:

- a. Gator is a real company, unconnected to KVK;
- b. KVK’s involvement with the paper-NDA was limited to acting as Gator’s agent and helping Gator file the application;
- c. KVK’s involvement with the paper-NDA ceased on May 29, 2015, when Gator purported to terminate KVK’s right to act on its behalf before the FDA; and
- d. Despite the Court’s October 2013 Order, the paper-NDA should not be withdrawn because it is “owned” by Gator, not KVK, and Gator should not be made to suffer for KVK’s breaches of the Novel-KVK Settlement Agreement

76. The FDA appears to have believed Gator and KVK, as it did not withdraw the application, and in fact gave it final approval to the paper-NDA on December 27, 2016.

77. The Court appears to have believed Gator and KVK, as it denied Novel’s request for

relief when KVK did not withdraw the application, as ordered by this Court after rejecting KVK's argument that it was without power to do so.

78. KVK's and Gator's statements to Novel, the FDA and this Court were false, both by commission and omission, as we now know from the documents released by the FDA on December 27, 2016 that:

- a. KVK is manufacturing, or is imminently set to manufacture, the generic powder formulation of SUPREP associated with the paper-NDA;
- b. KVK is, or is imminently set to be, the point of contact for any consumer questions about the generic powder formulation of SUPREP associated with the paper-NDA;
- c. KVK is, or is imminently set to be, the point of contact for reporting of any adverse effects suffered as a result of the generic powder formulation of SUPREP associated with the paper-NDA; and
- d. KVK continued and continues to work on the paper-NDA application, including acting as the "customer" with the printer preparing the packaging materials for the drug.

79. KVK and Gator made these misrepresentations to Novel, the Court and the FDA with malice and intent, so as to secure their ability to come to market with a generic formulation of SUPREP before Novel could do so.

80. KVK's and Gator's misrepresentations to Novel, to the Court and to the FDA, and the actions taken in reliance on those misrepresentations, have led to the present situation, where Gator and KVK are poised to release a generic powder-based formulation of SUPREP, to the severe and irreparable detriment of Novel.

81. Had it had proof of the true facts at the time, Novel would have taken immediate action to stop KVK and Gator from this wrongful course of conduct by submitting evidence of same to the Court and/or the FDA. Upon information and belief, had the FDA and the Court known the truth, they would not have allowed the present situation to result.

82. Novel has sustained significant damage as a direct result of KVK's and Gator's fraud, in amounts to be determined at trial.

**PRAAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully prays for judgment against Defendant as follows:

- a. For an order that KVK (and Gator, if it is found that Gator is the alter ego of KVK) has breached the Settlement Agreement;
- b. For an order that KVK willfully violated the Court's October 2013 Order;
- c. For an order that KVK and Gator have misappropriated, and continue to misappropriate, Novel's confidential and proprietary information;
- d. For an order that Gator has tortuously interfered with contractual relations, namely the Novel-KVK Settlement Agreement;
- e. For an order that KVK and Gator have committed a fraud upon Novel, the Court and the FDA;
- f. For an order that as a result of KVK's and Gator's actions, Novel has been damaged;
- g. For an order that KVK and Gator immediately withdraw and terminate the paper-NDA and any other application for a generic formulation of SUPREP;
- h. For an order temporarily, preliminarily and permanently enjoining KVK or Gator from proceeding any further with the paper-NDA or any application for a generic formulation of SUPREP;

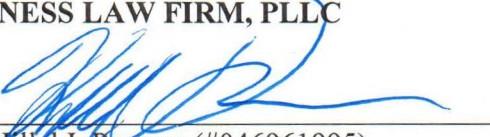
- i. For an order temporarily, preliminarily and permanently enjoining KVK or Gator from any action whatsoever in connection with a generic formulation of SUPREP;
- j. For an order directing KVK and Gator to pay money damages to Novel in an amount to be determined at trial;
- k. For an order directing KVK and Gator to pay punitive damages to Novel in an amount to be determined at trial;
- l. For an award of attorneys' fees and costs; and
- m. For such other and further relief as this Court may deem just and proper.

Respectfully submitted,

DATED: January 20, 2017

**PARNES LAW FIRM, PLLC**

By:

  
Hillel I. Parness (#046961995)

136 Madison Ave., 6<sup>th</sup> Floor  
New York, NY 10016  
Telephone: (212) 447-5299

*Attorneys for Plaintiff Novel Laboratories, Inc.*

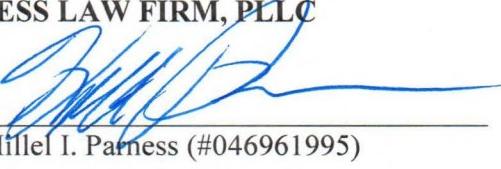
**CERTIFICATION PURSUANT TO RULE 4:5-1**

The undersigned attorney for Plaintiff certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any other New Jersey court. There are no pending arbitration proceedings. No other action or arbitration proceedings are contemplated.
2. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of their action that should be joined pursuant to R. 4:28.
3. I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

**PARNESS LAW FIRM, PLLC**

By: \_\_\_\_\_

  
Hillel I. Parness (#046961995)

136 Madison Ave., 6<sup>th</sup> Floor  
New York, NY 10016  
Telephone: (212) 447-5299

*Attorneys for Novel Laboratories, Inc.*

**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, Hillel I. Parness is hereby designated as trial counsel in their matter.

**PARNESS LAW FIRM, PLLC**

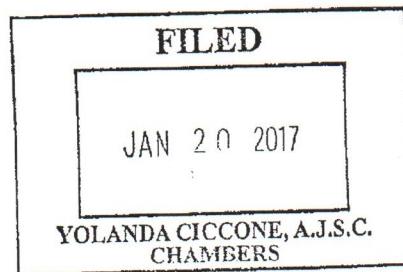
By:

Hillel I. Parness (#046961995)

136 Madison Ave., 6<sup>th</sup> Floor  
New York, NY 10016  
Telephone: (212) 447-5299

*Attorneys for Novel Laboratories, Inc.*

**PARNES LAW FIRM, PLLC**  
136 Madison Ave., 6<sup>th</sup> Floor  
New York, NY 10016  
212-447-5299  
*Attorneys for Plaintiff*



**NOVEL LABORATORIES, INC.,**

Plaintiff,

v.

**KVK-TECH, INC. and GATOR PHARMACEUTICALS, INC.**

Defendants

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: SOMERSET COUNTY**

**DOCKET NO. SOM-L-70-17**

*Amended*

**ORDER TO SHOW CAUSE FOR  
TEMPORARY RESTRAINING ORDER  
PURSUANT TO RULE 4:52  
AND FOR FURTHER RELIEF**

THIS MATTER being brought before the Court by Plaintiff Novel Laboratories, Inc. ("Novel"), seeking relief by way of temporary restraints pursuant to R. 4:52, based on the facts set forth in the attached Certification of counsel filed herewith,

It is on this 20<sup>th</sup> day of January, 2017, ORDERED that Defendants KVK-Tech, Inc. ("KVK") and Gator Pharmaceuticals, Inc. ("Gator") (KVK and Gator, collectively, "Defendants") appear and show cause before the Superior Court, Chancery Division, Somerset County, 20 North Bridge Street, 3rd Floor, Somerville, NJ 0887610 at 9 o'clock or as soon thereafter as counsel can be heard, on the 10<sup>th</sup> day of February, 2017, why an Order should not be issued:

- A. Preliminarily and permanently enjoining and restraining KVK and Gator from directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with 505(b)(2) New Drug Application ("paper-NDA") No. 204553, filed with the U.S. Food and Drug Administration ("FDA") seeking approval to market BC Powder for Oral Solution Kit, a generic powder version of Braintree Laboratories, Inc.'s

- SUPREP® Bowel Prep Kit (“SUPREP”) drug product;
- B. Preliminarily and permanently enjoining and restraining KVK and Gator from directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with developing, manufacturing, advertising, or selling, any generic versions or formulations of SUPREP, whether in liquid-concentrate form, powder form, or any other form now or hereinafter known or developed;
- C. Preliminarily and permanently enjoining and restraining KVK and Gator from directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with breaching, or aiding, abetting, inducing or encouraging any party to breach, the October 3, 2012 settlement agreement between Novel and KVK (the “Settlement Agreement”) in Novel Laboratories, Inc. v. KVK-Tech, Inc. and Amruthram, Inc., Docket No. C-12009-11 (“Novel v. KVK I”); and
- D. Preliminarily and permanently enjoining and restraining KVK and Gator from directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with breaching, or aiding, abetting, inducing or encouraging any party to breach, this Court’s October 10, 2013 Order in Novel v. KVK I;

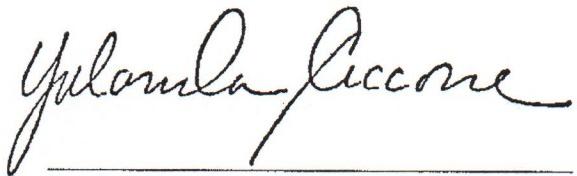
**AND IT IS FURTHER ORDERED** that, pending the return date herein, KVK and Gator are temporarily enjoined and restrained from:

- A. Directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with the paper-NDA; and
- B. Directly or indirectly proceeding in any fashion, or providing assistance to any other person, in connection with developing, manufacturing, advertising, or selling, any generic versions or formulations of SUPREP, whether in liquid-concentrate form, powder form,

\ or any other form now or hereinafter known or developed.

**AND IT IS FURTHER ORDERED** that:

1. Defendants may move to dissolve or modify the temporary restraints herein contained on two (2) days notice to Novel's counsel.
2. A copy of this Order to Show Cause and supporting Certification submitted in support of this application shall be immediately served upon Defendants by hand-delivery.
3. Novel shall file with the Court proof of service of the pleadings on Defendants no later than three (3) days before the return date.
4. Defendants may file and serve written papers in opposition to this Order to Show Cause by Feb. 3<sup>rd</sup>, 2017.
5. Novel may file and serve written papers in reply to any opposition filed by Defendants by Feb. 7<sup>th</sup>, 2017.
6. If Defendants do not file and serve opposition to this Order to Show Cause, this application will be decided on the papers on the return date and relief may be granted by default, provided that the Novel files a proof of service and proposed form of Order at least three (3) days prior to the return date.
7. If Novel has not already done so, a proposed form of Order addressing the relief sought on the return date must be submitted to the Court no later than three (3) days before the return date.
8. The Court will entertain argument, but not testimony, on the return date of the Order to Show Cause, unless the parties are advised to the contrary no later than three (3) days before the return date.



YOLANDA CICCONE, A.J.S.C.